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Notice of Allowability

0.14

Application No.

09/622,583

Examiner

Suryaprabha Chunduru

Applicant(s)

CAROSELLA ET AL.

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/24/03.
2. ☒ The allowed claim(s) is/are 2,3 and 16-24.
3. ☒ The drawings filed on 8/21/2000 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____. |
| 3 <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. _____ | 7 <input type="checkbox"/> Examiner's Amendment/Comment |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other _____. |


JEFFREY FREDMAN
PRIMARY EXAMINER

Art Unit: 1637

ALLOWED CLAIMS/ TJ

2. (Currently Amended) A method for establishing the HLA-G expression profile of a solid tumour with a view to selecting a treatment which is suited to said tumour or with a view to monitoring the evolution of said tumour, comprising:

- (i) removing a tumour sample,
- (ii) preparing a histological section from said tumour sample,
- (iii) labeling the uncultured tumour cells of the tumour sample obtained in (ii) with antibodies specific for HLA-G membrane-bound and soluble isoforms, and
- (iv) establishing the HLA-G expression profile of said tumour sample by detecting the labelled tumour cells.

3. (Currently Amended) A method for establishing the HLA-G expression profile of a solid tumour with a view to selecting a treatment which is suited to said tumour or with a view to monitoring the evolution of said tumour, comprising:

- (i) removing a tumour sample,
- (ii) lysing the uncultured tumour cells,
- (iii) contacting the uncultured lysed tumour cells with various antibodies directed against the class I HLA antigens so as to form HLA-G isoform/antibody complexes, and
- (iv) establishing the HLA-G expression profile of said tumour sample by detecting the complexes formed in step (iii).

16. (Previously Presented) The method of Claim 2, wherein the antibodies specific for HLA-G membrane-bound and soluble isoforms are monoclonal antibodies.

17. (Previously Presented) The method of Claim 2, wherein the HLA-G membrane-bound isoforms are HLA-G1, HLA-G2, HLA-G3 and HLA-G4.

18. (Previously Presented) The method of Claim 2, wherein the HLA-G soluble isoforms are HLA-G5 and HLA-G6.

19. (Previously Presented) The method of Claim 3, wherein subsequent to the contacting in (iii) the cells are immunoprecipitated.

20. (Previously Presented) The method of Claim 3, wherein the detecting in (iv) comprises electrophoresis and transfer to a membrane.

21. (Previously Presented) The method of Claim 3, wherein the antibodies specific for HLA-G membrane-bound and soluble isoforms are monoclonal antibodies.

22. (Previously Presented) The method of Claim 3, wherein the HLA-G membrane-bound isoforms are HLA-G1, HLA-G2, HLA-G3 and HLA-G4.

23. (Previously Presented) The method of Claim 3, wherein the HLA-G soluble isoforms are HLA-G5 and HLA-G6.

24. (Currently Amended) The method of Claim 3, wherein the uncultured tumour cells are labeled prior to lysing the tumour cells in (ii).

DETAILED ACTION

1. Acknowledgement is made for the request to establish continued prosecution application (RCE) filed on October 24, 2003. The request for RCE is accepted and is established with the status of the application as follows:

- a. the filling date of this RCE is established as 10/13/2000;
 - b. Claims 3-15 are canceled. Claims 2, 3, 16-24 are pending.
2. The Amendment filed on October 24, 2003 has been entered and considered.
3. Claims 2-3, and 16-24 are allowed.

The following is an examiner's statement of reasons for allowance:

The present invention is directed to a method for establishing HLA-G expression profile of a solid tumor comprising labeling uncultured tumor cells with antibodies specific for HLA-G membrane-bound and soluble isoforms and establishing the HLA-G expression profile of said tumor sample by detecting the labeled tumor cells. The closet prior art (Bensussan et al.) teaches detection of HLA-G expression in cultured tumor cells of a patient but did not teach detection of HLA-G expression in solid tumor cells, without culturing the tumor cells. Thus, the instant invention was not taught or obvious over the closest prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004

(new tel. No. 571-273-0783 effective from January 9, 2004). The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru.
November 21, 2003.



JEFFREY FREDMAN
PRIMARY EXAMINER